

METHOD FOR PRODUCING STERILE POLYNUCLEOTIDE BASED MEDICAMENTS

ABSTRACT OF THE DISCLOSURE

The present invention relates to a novel method for producing formulations comprising a polynucleotide, block copolymer and cationic surfactant. The formulations produced by the current method are suitable for use in polynucleotide based medicaments. A suitable method of production disclosed herein additionally comprises cold filtering a mixture of a polynucleotide, block copolymer and cationic surfactant, thereby sterilizing the formulation. The method of the present invention also eliminates the need for thermal cycling of the formulation, thereby reducing the time and expense required to produce large quantities of a formulation during commercial manufacturing. The present invention also relates to novel cationic lipids.